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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,928	08/27/2003	James Maxwell	1391-1602	1927

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EXAMINER
GRAFFEO, MICHEL

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/604,928	MAXWELL ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88 and 90-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-88 and 90-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 1-88 and 90-99 are pending and examined.

Applicant has amended claims 1, 3-8, 15-2030-31, 35-37, 41-45, 47-49, 59-67, 70-71, 74, 77, 83, 90 and 92, canceled claim 89 and provided arguments for the patentability of claims 1-88 and 90-99 in the response filed 16 December 2005.

Applicant's arguments, see response, filed 16 December 2005, have been fully considered and are persuasive. Therefore, the rejection of claims 3-8, 15, 17-20, 30-31, 35-36, 42-61 and 71-88 under 35 USC §112, have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made. Any rejection not specifically stated in this Office Action has been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn.

Claim Objections

Claims 3-8 are not clear to the extent that the edible film is not preceded by an article such as "the" and to such an extent it is not clear that edible film is the same as in the claim from which claims 3-8 depend.

Claim Rejections - 35 USC § 103

Claims 1-22, 24-88 and 90-99 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application No. 2005/0013902 to Pearce in view of Al-Zuhair et al. Pharmacological Studies of Cardamon Oil in Animals. Pharmacological Research , Vol 34, No. 1 /2, 1996.

Pearce teaches an edible film which include a pullulan-free edible film and confectionaries (in current claims 90-99; see paragraph 74) and chewable oral snacks and methods of making same (in current claims 1-22, 24-88 and 90-99; see paragraph 11) comprising film forming agents such as maltodextrin (in current claims3-5, 47, 65; see paragraph 59), alginates, carageenans (in current claims 10-12, 50-52; see paragraph 14), wood (in current claim 14; see paragraph 24), silicates, calcium phosphate (in current claim 15; see paragraph 24) wherein the film forming agents are present in an amount of from 10-90% (in current claims3-8, 47-49, 65-67; see paragraph 16) and further comprising triclosan (in current claims 22 and 26; see paragraph 121), zinc gluconate (in current claim 25; see paragraph 145), food acids such as citric, lactic and succinic acids (in current claim 28; see paragraph 147), sweeteners such as aspartame and glycyrrhizinate (in current claim 83; see paragraph

47-57), essential oils (in current claims 37-39; see paragraph 103), from .1 to 30% flavorings (in current claim 39; see paragraphs 39-46), lecithin and other emulsifying agents (in current claim 41; see paragraph 37-38), cooling agents (in current claim 86; see paragraph 36) and coloring agents (in current claim 33; see paragraph 79) wherein the product contain from 1-4% moisture (in current claim94; see paragraph 65) and further wherein the product can be made in part by heating it to about 45 degrees (in current claim 69; see paragraph 165).

Pearce does not specifically recite cardamom oil as a particular essential oil nor a method of cleansing the oral cavity.

Al-Zuhair et al. teach a method of using cardamom oil for multiple indications making use of its many favorable characteristics such as its antibacterial properties (in current claims 1-22, 24-88 and 90-99; see Introduction).

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine the references because Pearce teaches that essential oils can be applied in the edible film which directs one of ordinary skill in the art to use cardamom oil in particular because of cardamom oil's many beneficial properties. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application No. 2005/0013902 as applied to claims 1-22, 24-88 and 90-99 above

and further in view of US Patent No. 1,056,212 to Puetzer et al. (cited to show the state of the art at the time the application was filed).

Puetzer et al. teaches an antacid containing urea (see first page lines 27-28).

Claims 70-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,971,806 to Cherukuri et al. in view of Al-Zuhair et al. Pharmacological Studies of Cardamon Oil in Animals. Pharmacological Research , Vol 34, No. 1 /2, 1996.

Cherukuri et al. teach a chewing gum composition and methods of making same comprising:

- flavor oils and extracts derived from plants (see col 6 lines 59-64) present in an amount from 0.05-3.0% (see col 7 lines 44-45),
- up to about 90% maltodextrin (see col 5 lines 35-40),
- up to about 30% fillers (see col 5 lines 26-31 and col 4 lines 57-59) such as wood (see col 4 line 35), calcium carbonate, magnesium silicate, tricalcium phosphate and dicalcium phosphate (see col 4 lines 64-66),
- hydrocolloids such as alginates (of which one skilled in the art would find sodium and calcium to be obvious species), starch, pectin, gum arabic (see col 8 lines 15-21) wherein the starch pectin and gum arabic can be present in amounts of 0.1 to 12% (see col 8 line 45) and carrageenan (see col 5 line 22),

- a medicament (see col 9 lines 55-end) such as aspirin, fluorides and calcium carbonate (see col 10 Lines 1-6), food acids such as citric, adipic and tartaric acid (see col 5 line 25) and antacids (col 10 line 2),
- softening agents (see col 5 line 15) such as propylene glycol present in amounts up to about 30% (see col 4 lines 45-63),
- an effective amount of a colorant (see col 5 line 3),
- flavoring agents (see col 6 line 59) such as oils (spearmint) and synthetic flavoring oils (see col 6 lines 65-end) such as citrus oil (see col 7 line 3) or menthol (see col 7 line 8) present in an amount of from 0.05 to 3% (see col 7 lines 38-45),
- emulsifiers such as lecithin (see col 5 line 20), and,

high intensity sweeteners such as monellin and glycyrrhizin (see col 5 line 56).

One of ordinary skill in the art would have been motivated to combine the above references and as combined would teach the invention as claimed. One of ordinary skill in the art would have been motivated to combine the references because Cherukuri et al. teach that essential oils can be applied in the edible film which directs one of ordinary skill in the art to use cardamom oil in particular because of cardamom oil's many beneficial properties. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-88 and 90-99 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-99 of copending Application No. 10/604923. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the '923 Application claims a pullulan free edible film comprising a film forming agent and an effective amount of an antimicrobial agent. The limitations of each dependent claim of the '923 are recited verbatim as those in the instant application but for the specific antimicrobial agent used. Specifically, the '923 application claims a method of using a pullulan free edible film, a method of making a pullulan free edible film and a pullulan free edible film (formed for example into a candy comprising 1-4% moisture) comprising:

- 5-60% maltodextrin,

- 10-50% hydrocolloid selected from a natural gum (such as natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and zanthan gum), biosynthetic gum, a natural seaweed (with carrageenan), a natural plant extrudate, a natural fiber extract, a gelatin, a biosynthetic process starch, a cellulosic material, an alginate (such as sodium or calcium), a pectin or combinations thereof,
- 5-30% filler selected from microcrystalline cellulose, a cellulose polymer (additionally comprising wood), magnesium carbonate, calcium carbonate, ground limestone, a silicate (including magnesium or aluminum), clay, talc, titanium dioxide, a calcium phosphate (comprising mono-calcium phosphate, di-calcium phosphate, or tri-calcium phosphate) and combinations thereof,
- 1-25% citral,

- a medicament comprising an oral cleansing or breath freshening compound selected from the group consisting of a pH control agent (comprising urea), inorganic components for tartar or caries control (comprising phosphates or fluorides), a breath freshening agent (comprising zinc gluconate), an anti-plaque/anti-ginginviti- s agent (comprising chlorhexidine, CPC or triclosan), a saliva stimulating agent (comprising a food acid selected from the group consisting of citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric and combinations

thereof), a pharmaceutical agent, a nutraceutical agent, a vitamin, a mineral and combinations thereof,

- 0-20% a softening agent wherein the softening agent comprises a plasticizer including a compound selected from the group consisting of sorbitol, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrup and combinations thereof,

- a coloring agent,

- 0.1-20% a flavoring agent selected from the group consisting of essential oils (selected from the group consisting of citrus oil, spearmint oil, mint oil, clove oil, oil of wintergreen and combinations thereof), synthentic flavors, fruit essences, anise, flavor oils with germ killing properties (comprise menthol, eucalyptol, thymol and combinations thereof) and mixtures thereof,

- emulsifying agent wherein the emulsifying agent comprises lecithin, (C10-C18) fatty acids, monoacyl glycerides, di-acyl glycerides, ox bile extract, polyglycerol esters, polyethylene sorbitan esters, propolyene glycol, sorbitan monopalmitate, sorbitan monosterate, sorbitan tristerate, enzyme modified lecithin, hydroxylated lecithings and combinations thereof,

- a pyrophosphate or polyphosphate,

- a high intensity sweetener selected from the group consisting of, sucralose, aspartame, NAPM derivatives such as neotame, salts of acesulfame, altitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizinate, dihydrochalcones, thaumatin, monellin, and combinations thereof,

- a cooling agent selected from the group consisting of menthol, ethyl p-menthane carboxamide, N,2,3-trimethyl-2-isopryl-butanamide, menthyl glutarate FEMA 4006, menthyl succinate, menthol PG carbonate, menthol EG carbonate, menthyl lactate, menthone glyceryl ketal, menthol glyceryl ether, N-tert-butyl-p-menthane-3-carboxamide, p-men-thane-3-carboxylic acid glycerol ester, methyl-2-isopryl-bicyclo (2.2.1), heptane-2-carboxamide, menthol methyl ether and combinations thereof,

wherein the citral is encapsulated or spray dried and further wherein the composition is formulated to deliver at least 0.005% concentration of citral to the oral cavity.

Claims 1-88 and 90-99 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-128 of copending Application No. 10/604921. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the '921 Application claims a pullulan free edible film comprising a film forming agent and an effective amount of an antimicrobial agent. The limitations of each dependent claim of the '921 are recited substantially verbatim as those in the instant application but for the specific antimicrobial agent used. Specifically, the '921 application claims a method of using a pullulan free edible film, a method of making a pullulan free edible film and a pullulan free edible film (formed for example into a candy comprising 1-4% moisture) comprising:

- 5-60% maltodextrin,
- 10-50% hydrocolloid selected from a natural gum (such as natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and zanthan gum), biosynthetic gum, a natural seaweed (with carrageenan), a natural plant extrudate, a natural fiber extract, a gelatin, a biosynthetic process starch, a cellulosic material, an alginate (such as sodium or calcium), a pectin or combinations thereof,
- 5-30% filler selected from microcrystalline cellulose, a cellulose polymer (additionally comprising wood), magnesium carbonate, calcium carbonate, ground limestone, a silicate (including magnesium or aluminum), clay, talc, titanium dioxide, a calcium phosphate (comprising mono-calcium

phosphate, di-calcium phosphate, or tri-calcium phosphate) and combinations thereof,

- 1-25% geranoil,

- a medicament comprising an oral cleansing or breath freshening compound selected from the group consisting of a pH control agent (comprising urea), inorganic components for tartar or caries control (comprising phosphates or fluorides), a breath freshening agent (comprising zinc gluconate), an anti-plaque/anti-ginginviti- s agent (comprising chlorhexidine, CPC or triclosan), a saliva stimulating agent (comprising a food acid selected from the group consisting of citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric and combinations thereof), a pharmaceutical agent, a nutraceutical agent, a vitamin, a mineral and combinations thereof,

- 0-20% a softening agent wherein the softening agent comprises a plasticizer including a compound selected from the group consisting of sorbitol, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrup and combinations thereof,

- a coloring agent,

- 0.1-20% a flavoring agent selected from the group consisting of essential oils (selected from the group consisting of citrus oil, spearmint oil, mint oil, clove oil, oil of wintergreen and combinations thereof), synthentic flavors,

fruit essences, anise, flavor oils with germ killing properties (comprise menthol, eucalyptol, thymol and combinations thereof) and mixtures thereof,

- emulsifying agent wherein the emulsifying agent comprises lecithin, (C10-C18) fatty acids, monoacyl glycerides, di-acyl glycerides, ox bile extract, polyglycerol esters, polyethylene sorbitan esters, propolyene glycol, sorbitan monopalmitate, sorbitan monosterate, sorbitan tristerate, enzyme modified lecithin, hydroxylated lecithings and combinations thereof,

- a pyrophosphate or polyphosphate,

- a high intensity sweetener selected from the group consisting of, sucralose, aspartame, NAPM derivatives such as neotame, salts of acesulfame, altitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizinate, dihydrochalcones, thaumatin, monellin, and combinations thereof,

- a cooling agent selected from the group consisting of menthol, ethyl p-menthane carboxamide, N,2,3-trimethyl-2-isopryl-butanamide, menthyl glutarate FEMA 4006, menthyl succinate, menthol PG carbonate, menthol EG carbonate, menthyl lactate, menthone glyceryl ketal, menthol glyceryl ether, N-tert-butyl-p-menthane-3-carboxamide, p-men-thane-3-carboxylic acid glycerol ester, methyl-2-isopryl-bicyclo (2.2.1), heptane-2-carboxamide, menthol methyl ether and combinations thereof,

wherein the geranoil is encapsulated or spray dried and further wherein the composition is formulated to deliver at least 0.005% concentration of geranoil to the oral cavity.

The '921 and '923 applications recite different antimicrobial components in the composition. Nonetheless, one of ordinary skill in the art would find it obvious to substitute both the geranoil and/or the citral for the cardamom based on the teachings of Pearce et al. which in paragraph 137 states that with "various films, particularly where the film encapsulates or is layered with another material, it may be desirable to include ingredients, especially in the encapsulated or co-layered material, other than mere sweeteners and flavoring, such as a bacterial, antiseptic, antimicrobial..." Thus, one of ordinary skill in the art would make the obvious substitution of one antimicrobial for the other and the '921 and '923 applications obvious over the instant application.

Response to Arguments - 35 USC §112

Applicant's arguments, see Response, filed 16 December 2005, with respect to 35 USC §112 have been fully considered and are persuasive.

Response to Arguments - 35 USC §103

Applicant's arguments, see Response, filed 16 December 2005, with respect to 35 USC §103 have been fully considered and are persuasive to the extent that Cherukuri et al. are directed to a chewing gum and therefore not applicable to claims 1-69. Additionally, the rejections over the Pearce et al. reference have been withdrawn

since as Applicant's have pointed out, the Pearce et al. reference has an earlier priority date. The new rejections made are over new art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20 January 2006
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